Better Regulation or more Frustration?*

A critical analysis of the Commission's strategy of "Better Regulation" from a current food law perspective

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Simple and practicable legal rules are virtually everyone's desire; legal gobbledygook, however, is probably welcome only by a small faction of the lawyers' profession. Every legislator is faced with the same essential problem: How to create just, fair, adequate and acceptable law for everyone concerned without leaving wide gaps for crooks whilst simultaneously avoiding administrative suffocation. European legislators are well aware of this classic dilemma and have addressed it in their Comprehensive Strategy on Better Regulation. But do the concepts and promises contained therein hold true? This is the crucial question the authors deal with – from a current food law perspective. They examine the main features of the legislators' ideas, examine their compatibility with food law practice and focus on the resulting issues. Unfortunately during the course of their analysis they find more frustration than better regulation. Whilst detecting some points that could well be improved, they regret they cannot propose an easy solution to the core problem.

I. Better Regulation – simply explained

The title "Better Regulation – simply explained" captions a little brochure published by the European Commission in 2006[1]. This publication gives a short overview of a "Comprehensive Strategy on Better Regulation" launched by the Commission in order to "ensure that the regulatory framework in the EU contributes to achieving growth and jobs, while continuing to take into account the social and environmental objectives and the benefits for citizens and national administrations"[2]. According to the Commission's own words the "Better Regulation strategy is based on three key action lines:

- Promoting the design and application of better regulation tools at the EU level, notably simplification, reduction of administrative burdens and impact assessment.
- Working more closely with Member States to ensure that better regulation principles are applied consistently throughout the EU by all regulators.
- Reinforcing the constructive dialogue between stakeholders and all regulators at the EU and national levels"[3].

The brochure "Better Regulation – simply explained" deals with essential features of the strategy; it primarily tries to give answers to the question "What is the Commission doing to reduce 'red tape'?" with "a mix of different actions:

- introducing a system for assessing the impact and improving the design of major Commission proposals;

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* This publication is loosely based on a presentation delivered by one of the authors at a conference organised by a food manufacturer in Noordwijk on 30 June 2008.

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1 European Commission: Better Regulation – simply explained, available on the internet at: http://ec.europa.eu/governance/better_regulation/brochure_en.htm.

2 European Commission – Better Regulation: http://ec.europa.eu/governance/better_regulation/index_en.htm.

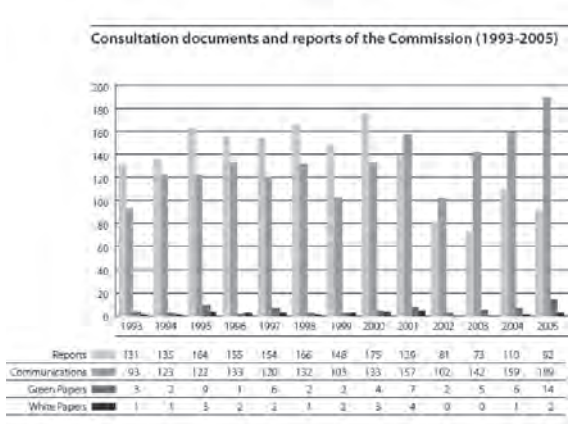
3 European Commission – Better Regulation: http://ec.europa.eu/governance/better_regulation/index_en.htm.

– implementing a programme of simplification of existing legislation;
– testing Commission proposals still being looked at by the Council of Ministers and the European Parliament, to see whether they should be withdrawn;
– factoring consultation into all Commission initiatives;
– looking at alternatives to laws and regulations (such as self-regulation, or co-regulation by the legislator and interested parties)"[4].

The publication goes on to deal with some of theses aspects more closely, particularly "1. Analysing impact," "2. Communicating and taking account of citizens' and companies' views", "3. Reducing paperwork", "4. Simplifying" and "5. Looking at Alternatives"[5]. The Commission concludes that "Better Regulation is an ongoing process – it will continue ... Making good laws and regulations is a challenge: public authorities at every level need to provide citizens and consumers with the security they expect, while at the same time creating the conditions to allow our businesses to compete more effectively and be more innovative in a highly competitive global environment. The European Commission is committed to striving for excellence in policymaking and regulation."[6].

II. Better Regulation – briefly examined

As can be seen, there are quite different interests that European legislators would like to balance: growth, jobs, social and environmental objectives and benefits for citizens as well as national administrations. No-one would object to these goals in general, but of course they do not always coincide. On the contrary: growth and jobs may well conflict with environmental objectives, and benefits for citizens are often at loggerheads with benefits for administrators. Surprisingly, food business operators are not expressly mentioned amongst the vital features of the better regulation strategy; however, they do appear in one of the key action lines, namely the proposed constructive dialogue between stakeholders and regulators. Furthermore they are mentioned as "companies" whose views and interests are to be taken into account: "The Commission has a long tradition of extensive consultation through various channels: Green Papers, White Papers, communications, fora ..., workshops, permanent consultative groups and consultations on the Internet[7]". Indeed, the Commission takes pride in the considerable number of consultations it has conducted over recent years[8]:



To see how ambitious the better regulation programme is, one merely has to take into account the gigantic numbers of participants involved with respect to food alone: Almost 500 million citizens, all of whom eat and drink, about 310,000 food businesses with a turnover of 870 billion € and employing 4.5 million people producing and marketing foodstuffs in altogether 27 Member States that are responsible inter alia for applying the legislation and supervising the industry, create a very confusing picture of potentially extremely different interests. Remarkable Green and White Papers have been put forward with respect to food law lately – for example the Green Paper "General Principles of Food Law" of 1997[9] and the White Paper "On Food Safety" of 2000[10], to name but the most important – and it cannot be said that there was no opportu-

4 European Commission: Better Regulation – simply explained, pages 6-7.

5 European Commission: Better Regulation – simply explained, pages 7-14.

6 European Commission: Better Regulation – simply explained, pages 16.

7 European Commission: Better Regulation – simply explained, pages 9.

8 European Commission: Better Regulation – simply explained, pages 9.

9 Doc. COM (1997) 176, as to which cf. Streinz, ZLR 1998, 145.

10 Doc. COM (1999) 719, as to which cf. Horst/Mrohs, ZLR 2000, 125, 129 and Horst, ZLR 2000, 475.

nity for stakeholders to comment. But have they also been heard and have their interests been taken into account properly?

The Commission is interested in whether "Better Regulation" works in practice, how it operates and what it can achieve. For this purpose it has had the programme independently reviewed by an "Independent Assessment Board"; the recent "Second Strategic Review of Better Regulation in the European Union" has only been published earlier this year[11]. According to the Commission's own perception this review "shows that real and substantial progress has been achieved" and "sets out plans for taking the process forward". In the Commission's own words:

"This Commission has given the highest priority to simplifying and improving the regulatory environment in Europe. This is part of its wider objective of delivering results to citizens and businesses. The Better Regulation Agenda, adopted in 2005, aims both to ensure that all new initiatives are of high quality, and to modernise and simplify the existing stock of legislation. In doing so, it is helping to stimulate entrepreneurship and innovation, to realise the full potential of the single market, and thereby promote growth and job creation. Better regulation is therefore a key element of the Lisbon Growth and Employment Strategy. The Better Regulation agenda also helps the EU to respond to globalisation, and to shape global regulation rather than to be shaped by it.

The Commission is making improvements at various stages of the policy cycle. Better Regulation does not mean deregulation or holding back new European rules when they are needed. But policy and regulatory proposals are now systemically assessed, and a wide range of options – regulatory and non-regulatory – are examined for each initiative. The quality of these assessments is overseen by an independent Impact Assessment Board. Existing laws are being simplified and codified, and a concerted effort is being made to reduce the administrative costs of EU laws. Pending proposals are being screened and withdrawn if they are no longer relevant or consistent with Commission priorities. In partnership with the Member States, a more effective approach is being developed to handle difficulties in implementing and ensuring conformity with Community law.

The Better Regulation Agenda is already bringing concrete benefits for businesses and consumers. But the full benefits will only be obtained if all European Institutions and Member States work together. This Communication reviews progress and highlights areas where further efforts are needed, and is an input to the European Council's stock-taking on better regulation in March 2008."[12]

The Commission then goes on to conclude:

"Much has been achieved in developing Better Regulation in the EU. Improving regulation and delivering benefits to citizens and business needs time, financial and human resources, and adjustment of institutional and administrative structures. This cannot be achieved without sustained political support. The Commission is strongly committed to playing its part, investing heavily in its Rolling Simplification Programme and its Action Programme for reducing administrative burdens, and continuously strengthening its impact assessment system. Ultimately success will depend on the commitment of the other European institutions, the Member States, local/regional authorities, and stakeholders, and the Commission calls on them to join this collective effort."[13]

Let us hereafter have a closer look at some of the more prominent examples of the over 80 measures of the White Paper on Food Safety that have been implemented and concluded since 1999. And let us in particular check whether the Better Regulation initiative has lived up to the aims set, namely simplification and the reduction of administrative burden on the basis of impact assessments intended to take proper account of stakeholders' interests and result in a legal framework that best accomodates consumers' interests as to food safety and information whilst ensuring the competitiveness of industry especially with regard to innovation. Many, not only within industry, think that this is not the case. On the contrary: Whilst impact assessments and "legislative red tape" have been increased considerably, not much has been achieved in terms of simplification, reduction of administrative burden and fostering competitiveness.

11 Second Strategic Review of Better Regulation in the European Union – Brussels 30.1.2008, COM (2008) 32 final, available on the internet at: http://ec.europa.eu/governance/better_regulation/index_en.htm.

12 Second Strategic Review of Better Regulation in the European Union, page 1.

13 Second Strategic Review of Better Regulation in the European Union, page 12.

III. Better Regulation – in practical terms

Undoubtedly the concept of Better Regulation is desirable as such. After all no-one would want the opposite, namely worse regulation, nor a complete persistence of present regulations. As there is always something to repair or to amend in legislation for mere practical necessity, the goal of a simultaneous improvement becomes virtually self-evident. The same can be said for the three key action lines. Particularly simplification apparently makes life easier for almost everyone and the reduction of administrative burdens can certainly release more economic freedom. The different actions envisaged by the Commission are also welcome and beneficial at a first glance. Impact assessment is a vital tool for analysing how regulation works in practice, especially to what extent it is achieving the desired effects. Of course it is vital in this respect to thoroughly test proposals, to take into account the views of business operators as well as consumers and to consider potential alternatives.

However, as so often in the legislative process, it is not so much the common goals which are lacking, but rather the different options and the details of individual regulations which cause most of the problems. When looking at current food legislation one can observe a number of features which under scrutiny show flaws of the comprehensive Better Regulation strategy.

To assist the civil servants that actually have to work out proposals for legislation, a series of practical guidance documents have been developed within the Commission. In the area of food law the "Guidelines for the preparation of a SANCO SCOPING PAPER"[14] set the scene and have been the basis for the development of legislation since 2005.

It gives all the necessary elements for a Better Regulation approach, namely helping to identify the "issue at stake", be it a legal obligation to revise the legislation, a political commitment, a stakeholder suggestion, new data, a scientific development or others. It goes on to assist in defining the objectives to be achieved on the basis of DG SANCO's mission according to the Treaty, i.e. to empower consumers, to protect and improve human health, to ensure food to be safe and wholesome, to protect the health of animals and plants and to promote the humane treatment of animals. Objectives should be "SMART" (Specific, Measurable, Accepted, Realistic and Time-dependent) and correspond not only to the issues at stake but also indicate how they relate to the more general Commission objectives as the Lisbon Strategy.

The policy options available have to be identified and assessed, be it "do-nothing (i.e. no change), self-regulation (code of conducts, voluntary standards/agreements), guidelines, market-based instruments (taxes, subsidies, and user fees), co-regulation (self-regulation + regulatory framework), information and education campaigns, expenditure of DG SANCO funds, co-operation with Member States or other bodies, broad policy-defining documents (White Papers, Action Plans, Communications, etc.), legislation (regulation, directive or, rarely, decision, as defined in article 249 of the EC Treaty, including streamlining/thinning existing legislation or subordinate legislation i.e. a Commission act)". Whilst being last in the list, it has to be noted already that legislation still is the measure of choice in almost all instances and that all the other policy options or instruments are rarely or never used, at least not in the area of food law or at least not to the authors' knowledge.

Likely economic, environmental and social impacts have to be identified and here indeed regards shall be had at "competitiveness of EU firms, effective competition between market participants, SMEs and administrative burden falling upon the Community, national governments, regional and local authorities, economic operators and citizens". Timescale, likelihood and magnitude of impacts are to be assessed. And finally all respective advantages and disadvantages of the different policy options have to be assessed before a proposal is to be finalised. It is all there, up to "Flow Charts" and a "Listing of Impacts" that need to be considered. But how does it work out in practice?

IV. Better Regulation – pretence and reality

Of the more than 80 legislative measures that have been introduced in the follow up to the White Paper of Food Safety, a closer look shall be had at the Regulation (EC) No. 1924/2006 on nutrition and

14 Guidelines for the Preparation of a SANCO Scoping Paper DG SANCO – 2005 – Brussels: DG SANCO, not published.

health claims made on foods (Claims-Regulation)[15] and at the current Commission proposals for Regulations on novel foods an amending the Regulation (EC) No. XXX/XXXX (common procedure) (new Novel Foods Regulation)[16] and on the provision of food information to consumers (Food Information Regulation)[17]. Even though the latter two are still proposals and need to pass the legislative process, they have "profited" from the Better Regulation approach within the Commission and were indeed developed with regard to all the means and aims set out therein and are therefore rather ideal objects of scrutiny as to the effectiveness of the Better Regulation efforts or DG SANCO.

The impact assessments of the Commission can be found on the pertaining websites and often amount to works of about more than one hundred pages each[18]. However, what about the effectiveness of those impact assessments with regard to Better Regulation? What were the issues at stake from a stakeholder or legislator perspective? And how were they dealt with and resolved? Let us take these three examples one by one:

A. Claims-Regulation

The Claims-Regulation has been designed and agreed with the aim of establishing detailed provisions and principles for the use of nutrition and health claims on foods[19] that go beyond the general principles established in Directives 2000/13/EC and 84/450/EC, namely that all claims including nutrition and health claims shall not be false, ambiguous or misleading as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production, or, by attributing to the foodstuff effects or properties which it does not possess.

Even though the original Commission proposal[20] experienced many changes and amendments in the legislative process, the essential legislative approach that shall hereafter be scrutinized as to its compatibility with the Better Regulation exercise has remained the same, namely

- all nutrition and health claims need a Community authorisation before they can be used,
- all foods on which nutrition and health claims are to be made need to comply with nutrient profiles defining standards on nutritional composition as prerequisites for the use of nutrition and health claims,
- and a new category of health claims is being established that in most Member States have previously been regarded as unlawful, namely reduction of disease risk claims.

A lot of other provisions and details are included in the Regulation, but where stakeholders and legislators strongly disagreed during the process from the first discussion paper of DG SANCO through to the final adoption of the Regulation were those three:

- Is it justified to introduce such a prohibitive system for all nutrition and health claims where each and every claim needs do undergo a full authorisation procedure, or would it be more appropriate to restrict that prohibitive approach to the new disease risk reduction claims and maintain the established system hitherto in place for all other nutrition and health claims? And if authorisation is deemed necessary, what procedures would be proportionate, pure authorisation or "lighter" procedures like mere notification, at least for certain claims?
- Is it justified to prohibit claims otherwise true and justified on foods solely because the composition of those foods does not meet nutritional standards defined in nutrient profiles, or would it be more appropriate to let the obligatory nutrition information on all foods with nutrition and health claims suffice to inform consumers on the "overall nutritional status" of the food on which the claims are being made?

15 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF.

16 http://ec.europa.eu/food/food/biotechnology/novelfood/COM872_novel_food_proposal_en.pdf, the reference to the Regulation (EC) XXX/XXXX refers to the Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings: http://ec.europa.eu/food/food/chemicalsafety/additives/com2006_423_en.pdf.

17 http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/3359-en.pdf.

18 http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm, http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm, http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm.

19 cf. Loosen, ZLR 2006, 521, Hagenmeyer, EffL 2006, 233 and StoffR 2007, 201

20 http://europa.eu/eur-lex/en/com/pdf/2003/com2003_0424en01.pdf.

– Is it justified to allow for claims being made that communicate reduction of disease risk properties whilst all claims attributing to foodstuffs the property of preventing, treating or curing a human disease are and remain prohibited or is the borderline between those claims so blurred that from a consumer perspective they are indistinguishable and should both remain prohibited?

Whilst regarding the first two questions industry opted on what they thought were the more proportionate options that would have avoided a lot of especially bureaucratic and administrative burden and were finally not heard, it was the consumers who had strong reservations on reduction of disease risk claims that remained part of the Regulation nonetheless. Notification and/or optional authorisation procedures for nutrition and health claims other than reduction of disease risk claims were proposed and rejected after initial support from the European Parliament and some Member States, and obligatory nutrition declaration for all foods on which claims are made was argued to being sufficient safeguard for proper consumer information and equally rejected, again after initial support from the European Parliament and some Member States. Comparably consumers were not successful in their opposition to reduction of disease risk claims, the procedures foreseen being taken as sufficient guarantee for consumers' protection from disease related claims in the sense of Art 2 Directive 2000/13/EC.

It is too early for a final assessment on what the Better Regulations would and should have been as a result of the Commission's Better Regulation initiative already in the then Commission proposal for the Claims-Regulation. All options and arguments had by then been debated, but as of now and almost two years after the publication of the Regulation neither complete nutrition or any health claims lists nor nutrient profiles have been agreed and not even one single reduction of disease risk or other health claim has been authorised. What is apparent, however, is that the Regulation has all but reduced the bureaucratic or administrative burden with regard to establishing the lawfulness of nutrition an health claims, and has rather prepared a legislative environment stifling innovation and competitiveness in that context. No one has counted the many thousand working hours that have gone into the development of the industry proposals for lists of nutrition and health claims and nutrient profiles and no one has counted those that have gone into the establishment of an Article 13-list now to be evaluated by EFSA and equally nutrient profiles and test-baskets of products on which to test them against. The numbers alone are impressive: 44.000 claims have been collected by industry within the 27 Members States and were sent to the Commission and 2.800 then on to EFSA, 800 of which stemming from a joint European industry list and many more from individual companies' contributions. Many thousand scientific references have been gathered and screened by industry and are now being assembled to concise scientific dossiers to be sent to EFSA as basis for their scientific evaluation. Many thousand food products of all kinds have equally been screened as to their composition and nutrition composition with regard to eventual profiles. EFSA has contributed to that process with scientific guidance for applications and profiles and is now engaged in a constant dialogue with the Commission in further developing nutrient profiles and lists. It is, to date, more than likely that all deadlines set will be missed, be it for nutrient profiles, be it for the establishment of claims lists. It seems therefore justified to come to the conclusion that, certainly, almost no approach can be imagined which would have been more restrictive and burdensome and therefore to the detriment of the competitiveness and innovativeness of industry. A more realistic assessment of the bureaucratic burden or "overkill" as some say[21] would have almost forced the Commission to shy away from the total prohibition of all nutrition and health claims it has not explicitly authorised – a feature still unparalleled worldwide (!) – and leave some of the responsibility to those responsible by virtue of Article 17 of Regulation (EC) No 178/2002, industry and Member States' authorities. A final assessment will only be possible once the basic elements of the Claims-Regulation are in place and effective in practice, Article 27 of the Regulation foresees a first formal review by 2013. But already today it would come as a surprise if the outcome of that assessment did not lead to the conclusion that, by all means, the legislative aims could have been achieved with far less bureaucracy, "lighter" procedures and more responsibility for those that apply

21 cf. e.g. Hagenmeyer, EffL 2008, 165, albeit in context with the Food Information Regulation.

and less burden for those that make the law and/or need to initiate the relevant approval and authorisation procedures.

B. "New" Novel Foods Regulation

Still under discussion in first reading in European Parliament and Council, the Commission proposal for a "new" Novel Foods Regulation has been drafted after a thorough impact assessment of the "old" Novel Foods Regulation (EC) No 258/97 with a view to, inter alia, better define and clarify the definition of novel food, introduce a procedure to collect information on the novelty of a food, create a centralised European procedure for the assessment of novel foods and establish a "lighter" authorisation procedure for traditional food from third countries for which the safety assessment can broadly be based on history of safe food use in the country of origin.

Whilst there is wide agreement that the current definition needs refinement and that authorisation procedures require overhaul and centralisation to become more effective and speedier and that traditional foods demand separate consideration, there is once again considerable disagreement on whether the Commission's proposal delivers what it is supposed to, Better Regulation to achieve the legislative aims with the least bureaucratic approach that assures consumer protection just as effectively as it fosters innovation and competitiveness of food business operators in the EU.

During the impact assessment industry commissioned an "Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector"[22], which was presented to the Commission and other stakeholders. This analysis identified three impacts of the current Novel Foods Regulation that contribute to explaining why food companies tend to attach a lower priority to the EU market for novel product development relative to other markets (e.g., the US). Those were:

– Firstly, the risk of delays of an average of three years (often even up to five years) in obtaining approval has devalued some investments and significantly diminished the economic incentive to bring products to the EU market.
– Secondly, the current approval mechanism encourages companies to be followers to the market rather than innovators; followers to the market experience lower costs and risks than novel food innovators and hence can easily earn higher rates of return than innovators.
– Thirdly, uncertainty about the timing of approval or the legal status of novel products exacerbates risks and adds cost, further diminishing the economic incentive to bring products to the EU market.

Industry therefore concluded that if the new Novel Foods Regulation is to create an environment encouraging novel product innovation, each of these deficiencies should be addressed. The time taken to approve/authorise a novel food should be reduced, incentives, e.g. exclusive access to markets or compensation for data provision, to encourage innovation should be considered and uncertainties relating to approval procedures and timing and legal uncertainties should be minimised.

What the Commission delivered is almost exactly the opposite of what industry had asked for:

– The definition of novel food was reduced to the notion that a food had not been used for human consumption to a significant degree within the Community before 15 May 1997, whereas before it had to belong to one of a limited number of product categories that described novelty with reference to at least a possible relevance for the safety of the food.
– The two existing approval procedures – notification and authorisation – were replaced by a single authorisation procedure, eliminating thereby the "lighter" notification procedure by one, however European and centralised, authorisation procedure.
– The applicant-linked authorisation was replaced by authorisation decisions of a general nature, from which all food business operators benefit, and a clause on data protection was only included after heavy lobbying from industry, in terms however that while protecting the data used for the application leave the general nature of the authorisation untouched; it is therefore of no use to the applicant who is still confronted with competitors making use of the authorisation.

22 Briefing Paper, Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector, Graham Brookes, July 2007.

Discussions are ongoing and there is bewilderment about a definition of novel food so broad that the Commission itself felt it necessary to clarify in recital 8 "the reformulation of food products produced from existing food ingredients available on the Community market, in particular by changing the composition or amounts of those food ingredients, should not be considered as novel food". In other words: a new recipe does not make a novel food, this is remarkable.

Industry is now explicitly asking for all elements again it had asked for during the initial impact assessment: the revision of the Regulation to stimulate innovation in the food and drink industry, protect both the functioning of the internal market and public health, and at the same time facilitate market access for novel food products by, inter alia, a relevant definition of novelty, establishing a more explicit link between a novel food authorisation and the applicant company either by going back to applicant-linked authorisations or by clarifying that the initial applicant be authorised to market the food for five years before it becomes a generic authorisation which can be used by others. In addition, an operable relationship between Novel Foods and Claims-Regulation and their relevant approval procedures will be asked for so that a novel food can be launched with the requested claim. And finally also the re-introduction of a simplified notification procedure is necessary not only for traditional foods from third countries, but for all foods and ingredients with a history of safe use, such as foods and ingredients to be used for other purposes or otherwise "substantially equivalent".

A first assessment of the Commission proposal against the background of the Commission's Better Regulation initiative from an industry perspective can therefore only come to the conclusion that the proposal is a complete disaster. Apart from the centralisation of the approval procedure none of the points raised in the impact assessment have been taken on board. The proposed definition would be useless, the procedure would be prolonged and not shortened, not least because of the involvement of the European Parliament in the regulatory procedure with scrutiny and the abolition of the notification procedure; moreover, the return on investment would be made impossible by the general scope of the authorisation. Thereby the "new" Novel Foods Regulation would essentially exclude innovation through novel foods in the European Union.

What the Commission has done, is follow Member States' requests for changes in the legislation that merely accommodate their application of the current Novel Foods Regulation, where the definition was reduced to one of consumption before May 1997, initial assessments were never accepted and the notification procedure disliked, the workload stemming from individual applications criticized and a novel foods catalogue being developed that shall now be introduced into the legislation. It also considers international pressure from third countries which find the current Novel Foods Regulation in conflict with international agreements. Certainly this is not a good example for the effectiveness of the Commission's efforts on Better Regulation either and it remains to be hoped the ongoing deliberations in Council and Parliament will succeed in improving the proposal.

C. Food Information Regulation

Much has already been written and said on the current Commission proposal on the provision of food information to consumers[23] and not all of it shall be repeated here again. However, with regard to Better Regulation the following points must be raised: What industry had asked for during the process of evaluation and impact assessment was improvement of existing legislation by simplification, establishment of, inter alia, better understandable and applicable provisions, the abolition of superfluous labelling elements such as the double labelling of certain additives, concrete proposals for differentiating between information to be provided on and off label, recognition of its voluntary approach and commitment to nutrition labelling. Industry had not requested ever new labelling obligations that were on other stakeholders' lists: origin labelling, animal welfare labelling and other labelling elements of an ethical or otherwise motivated origin, traffic light or other signposting labelling, detailed provisions on legibility perceived as impracticable and not ever more competences for the Commission to introduce new labelling obligations on elements of voluntary information that is hitherto not regulated in detail, but left to the food business operators and ultimately the courts

23 cf. e.g. Hagenmeyer, EffL 2008, 165; Schwinge, ZLR 2008, 31.

to be judged against the general prohibition to mislead consumers.

What the Commission delivered was merely exactly what the industry had not wanted: Ever more provisions which were not improved as to their legibility and application including a provision on a minimum font size of 3 mm perceived by almost all stakeholders as being impracticable, an obligation for nutrition labelling incompatible with current industry initiatives and questionable as to its choice of nutrients and extent with no apparent scientific backing by EFSA or others, numerous provisions for the establishment of new labelling obligations, a new obligation for origin labelling, and extended competences for Member States to establish labelling provisions and regulations inter alia with regard to nutrition labelling that contradict the legislative aim of harmonisation.

Of course, all or many of those new elements were demanded by consumers or other stakeholders. It seems, however, that the Commission has not only lost its focus with regard to harmonisation, but also disregarded its very own principles of Better Regulation. It may not be as obvious and clear as in the case of the proposal for a new Novel Foods Regulation. If, however, such an eminent proposal leads to no other changes than additions to labelling obligations, when it was almost consensual agreement that consumers were today already provided with too much rather than too little information and the only attempt to simplification is a transferral of the more complicated and detailed provisions to the Annexes to the Regulation, then this is just not reaching the Commission's own standards with regard to Better Regulation. Less labelling obligations would have been the expectation, not paving the way for ever more obligations.

What are the reasons for this apparent failure to live up to the confessions to better regulate, foster innovation and promote a competitive legislative environment which can be observed in all three aforementioned peaces of (draft) legislation? Some suggestions are made hereafter.

V. Better Regulation – pretence or reality?

It is most of all the legislators' ambition to venture beyond the well established core purposes of European food law, namely food safety (or health protection, which is essentially the same objective) and the avoidance of deception, both as codified in Articles 1, 5-8, 14 and 16 of Regulation (EC) No. 178/2002 laying down general principles and requirements of food law[24]. An increasing number of recent European food law provisions and proposals are now aimed at a healthy and varied diet, which can be seen for example from Recital 3 and Article 6 para. 3 of Directive 2002/46/EC on food supplements[25], Recital 1 and Art. 10 para. 2 of Regulation (EC) No. 1924/2006 on nutrition and health claims[26], Recital 2 and Art. 7 para. 1 of Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods[27].

Furthermore the legislators openly take issue with "potentially undesirable effects" in Recital 10 of Regulation (EC) No. 1924/2006, namely consumers making "choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice". Most recently the Commission has put forward the idea that "the effectiveness of nutrition labelling can be strengthened as a means to support consumers' ability to choose a balanced diet"[28] and has suggested accordingly in Recital 32 of the Proposal for a Regulation on the provision on food information to consumers[29] that "mandatory nutrition information should assist action in the area of nutrition education for the public and support informed food choice". It is clear that health education is thus appearing as a new goal of European food legislation and that it shall be reached through compulsory labelling on the one hand and advertising bans on the other hand. An additional feature of the new legislative aims is the belief in science and the resort to ever more scientific substantiation as can be seen for example particularly from Articles 1, 6 and 7 of Regulation (EC) No. 178/2002 or Art. 4-6 of Regulation (EC) No. 1924/2006.

24 OJ L 31/1 of 1.2.2002.

25 OJ L 183/51 of 12.7.2002.

26 OJ L 404/9 of 30.12.2006, fully replaced by the corrected version in OJ L12/3 of 18.1.2007; cf. Loosen, ZLR 2006, 521, Hagenmeyer, EffL 2006, 233 and StoffR 2007, 201.

27 OJ L 404/26 of. 30.12.2006; cf. Hagenmeyer/Loosen, EffL 2007, 189.

28 COM (2008) 40 final, 30.1.2008, Explanatory Memorandum, page 2.

29 COM (2008) 40 final, 30.1.2008.

The crucial question from a Better Regulation perspective must now of course be whether the new goals can in fact be reached with the envisaged means and whether expert-stakeholders' views have been or are being taken into account properly. Are there alternatives to the current and the proposed rules which might be more suitable and more effective? And what is more: Do the legislators meet their own scientific standards when legislating? All recent EU legislation contains so-called evaluation or review clauses, the purpose of which is to commit legislators to speedily reconsider whether or not legislative aims and goals have been achieved. Taking the example of Art. 27 of Regulation (EC) No. 1924/2006 which demands an evaluation of current nutrition and health claims law by 19 January 2013 together with a proposal for amendments if necessary: "The report shall also include an evaluation of the impact of this Regulation on dietary choices and the potential impact on obesity and non-communicable diseases". If the European legislator were to really listen to stakeholders, this is where a review of some of the most striking errors of the Claims-Regulation might take off.

VI. More frustration – potential explanations

So why are things as frustrating as they are? Of course there are numerous reasons, all of them coming together in the regulatory process. Two main problems in the view of the authors stem from democracy and media, both of which can neither be complained about nor done away with. In a democratic society it is immanent in the political system that anyone can voice his or her opinion and that politicians are dependant on the support of majorities. This leads to the necessity of attempting to influence opinions by way of democratic parties, political pressure groups and lobbying organisations. Since politicians in their capacity as legislators do not only have to represent all those different opinions, which regularly are only partially borne out by experts, but also have to be seen as active decision makers in the public eye of the media, all kinds of compromises are unavoidable. Often only the smallest common denominator is agreeable, particularly on a European level, and it appears mostly impossible to only heed common sense. Politicians not seen to be acting, i.e. legislating, are prone to lose their essential support. One is reminded of Milton Friedman's theory that economic crises are actually caused by politicians trying to be re-elected, an idea that amongst others was held worthy of the Nobel Prize in 1976.

More specifically, it would seem that all the best intentions with regard to Better Regulation are futile when they are not reflected in the division of powers that represent the eventually conflicting interests. Paper is patient, as the German proverb goes, and eminent Better Regulation initiatives are prone to fail as long as they are restricted to measures that rather serve to self-control and discipline the legislators in charge. That way Better Regulation merely assures all interests have been heard and taken notice of. What it fails to deliver in many cases, especially when issues become "political" such as health and consumer safety, is balanced legislative proposals that duly reflect the eventually conflicting interests, in the case of food law those of consumers, industry and authorities. This is the authors' experience of the last ten years of food law proposals from the Commission and legislation enacted.

What appears necessary to make the Commission's Better Regulation initiative a success in the area of food law is a re-balancing of powers within the Commission. It is now DG SANCO that is in charge, with DG ENTERPRISE restricted to rather limited control functions. Naturally DG SANCO takes consumers' interests first and has to. A shared responsibility between the two Directorates General would be one option to institutionalise a more balanced approach in the area of food law. That would not necessarily result in Better Regulation, but it might well serve this purpose, as institutionalisation and procedural backing can ascertain good intentions are really taken on board and seriously, when it comes to deciding individual issues. Since food law concerns the food industry as much as consumers it would seem a sensible idea to share responsibilities between the two Directorates General that once were (DG ENTERPRISE) and now are (DG SANCO) in charge.

And then, from a lawyer's perspective, it would be desirable that the Commission's legal services finally gain more influence than they currently have. From the authors' experience the legal services are now being restricted to rather formal checks and have no say whatsoever with respect to details of substantive law. If Better Regulation is meant to be more than checking whatever balance

of interests has been achieved, but could leave room for checking consistency and practicability of the provisions proposed, the quality of the law as such, a lot could be gained. If those two aspects of Better Regulation were taken on board, the reflection of the potentially conflicting interests in the division of powers within the Commission and the strengthening of the legal services with regard to their hold on better law making, the Better Regulation initiative of the Commission might have a much better chance of success, at least in the area of food law.

One final, more general example may serve to demonstrate the authors main point of criticism: On 1 July 2003 a revolutionary idea was proposed to the German Federal Parliament[30] under the caption "Dare freedom – abolish red tape". It suggested that parliament should decide "Germany is suffocating because of too much state" and put forward the idea of "strengthening individuals' responsibilities" whilst "restricting the state to its core tasks". A ten point programme was put forward in order to achieve the desired effects:

1. Automatic examination of new legislation.
2. Limitation of new legislation in time.
3. Reverse burden of proof for the continuation of legislation.
4. Automatic lapse of administrative rules and regulations.
5. Shortening of authorisation procedures.
6. Less judge-made law.
7. Regional experimenting and opening clauses.
8. Less EU-bureaucracy.
9. Self control of the German Federal Government.
10. Self control of the German Federal Parliament.

Anyone who reads the four page document in detail will surely applaud – the implementation of the ten proposals altogether would be a welcome relief to consumers as well as industry, because it would leave scope for business development and thus bring benefits for everyone. Now why, you might ask, did the German Federal Parliament not decide as proposed? The answer is as simple as revealing: The legislative initiative was promoted by someone who was in opposition to the German Federal Government at the time – her name is Angela Merkel. Today she is in power, but – as so many politicians – appears to have either completely forgotten what she stood for merely five years ago or to be fully tied down by political pressure from different directions. Her current Consumer Protection Minister's ever changing attitude (or mood?) to traffic light labelling is a striking feature of this dilemma. But perhaps we are all part of the problem, be it in our capacity as consumers, be it in our professional capacities. So, without suggesting to give up all hope, the authors would like to conclude: Explanations are there, "Better Regulation" remains something similar to a Fata Morgana, but in food law practice real frustration remains.

30 Deutscher Bundestag, Drucksache 15/1330 of 1.7.2003.